REMARKS

I. Introduction

Receipt is acknowledged of a non-final office action dated February 24, 2004. In the action the Examiner rejected claims 11, 31-32, 34 and 36-43 as allegedly not enabled and failing to meet the written description requirement.

II. Status of the Claims

In this response applicants amended claim 11 and added new claims 58-68 to further define claim scope. Support for the amended claim can be found on page 14, lines 4-5, of the present specification. Support for the new claims can be found throughout the specification, and on pages 14, lines 4-5, of the specification (claims 58-59), page 12, lines 21-25 (claims 60-61), and in originally filed claims (claims 62-68). Upon entry of this amendment, claims 11, 31-32, 34, 36-43, and 58-68 will be under examination.

Because the foregoing amendments do not introduce new matter, entry thereof by the examiner is respectfully requested.

III. Rejection of the Claims Under 35 U.S.C. § 112, first paragraph

A. Written Description Rejection

Claims 11, 31-32, 34 and 36-43 were rejected under 35 U.S.C § 112, first paragraph, as allegedly failing to meet the written description requirement. Office Action at 1-2. In particular, the examiner stated that "[o]ther than this single disclosed species of the claimed genus [*i.e.*, an antibody that binds a polypeptide of SEQ ID NO: 1], the specification fails to describe any additional species, which in this case encompasses species that are widely variant." Office action at 3. Applicants respectfully traverse this ground for rejection.

1. The application provides written description for the antibodies recited in claim 11

A skilled artisan would recognize that the specification is sufficiently described to support that applicants were in possession of an antibody that binds to: (a) a polypeptide consisting essentially of SEQ ID NO: 1, (b) a polypeptide with protein phosphatase activity comprising a sequence at least 90% identical to SEQ ID NO: 1, (c) an enzymatically active fragment of SEQ ID NO: 1, and (d) an immunogenic fragment of SEQ ID NO: 1.

For example, a polypeptide that shares 90% sequence identity with SEQ ID NO: 1 is described in the originally filed claims and on page 14 of the present specification. In addition, the specification sets forth conservative amino acid substitutions and describes a computer program which is employed to determine which amino acid residues can be altered without abolishing biological or immunological activity. Specification at 12.

2. The application sufficiently describes polypeptides comprising phosphatase activity that share at least 95% sequence identity with SEQ ID NO: 1

Moreover, a skilled artisan would know what amino acid changes to make so as to "produce a silent change and result in a functionally equivalent protein." Specification at 6. Functionality of the protein can then be determined based on known methods. Indeed, the polypeptide that is at least 95% identical to SEQ ID NO: 1 must have phosphatase activity. Thus, based on the teachings of the specification, a skilled artisan would readily be able to measure the activity of such PROPHO variants by following the assay described in example X. See specification at 51.

In addition, the specification describes which amino acid substitutions can be made to an amino acid sequence "which produce a silent change and result in a functionally equivalent PROPHO." Specification at 6, lines 11-12. Therefore, polypeptides comprising phosphatase activity and sharing at least 90% sequence identity with SEQ ID NO: 1 are sufficiently described. But in the interest of expediting prosecution, and without acquiescing to the examiner's rejection, applicants have amended the claims to recite 95% sequence identity.

3. The application describes polypeptide fragments of SEQ ID NO: 1 that comprise immunogenic or enzymatic activity

Likewise, antibodies that bind an immunogenic or enzymatically active fragment of SEQ ID NO: 1 are also described in the present application. Foremost, one of skill in the art would know what is meant by an immunogenic or enzymatically active fragment and would know how to assess the "immunogenic" or "enzymatically active" functionality as recited in the claims. In addition to prior art methods, the specification describes immunoassays which can be used for screening antibodies with a desired specificity (specification at 29, lines 8-14) and one of skill in the art could readily determine by prior art methods which fragments of SEQ ID NO: 1 are immunogenic. See specification at 51-52.

The specification also describes an assay for assessing PROPHO activity and this assay can be used to test the presently claimed fragments of SEQ ID NO: 1. *See* specification at 51. Likewise, enzymatic activity such as phosphatase activity can be assayed by known methods.

Furthermore, the examiner stated that the term "with" as recited in the claims is "inclusive or open-ended" and does not exclude additional unrecited elements. Office action at 4. In the interest of expediting prosecution, applicants amended claim 11 to recite the phrase "consisting essentially of." Applicants trust that this amendment addresses the examiner's concerns.

For at least these reasons, Applicants' claims satisfy the written description requirement of § 112, first paragraph, and therefore, withdrawal of this ground for rejection is respectfully requested.

B. Enablement Rejection

Claims 11, 31-32, 34 and 36-43 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly being non-enabled. Office Action at 4-5. Specifically, the examiner stated that the specification is "enabling for an antibody that binds to SEQ ID NO: 1, [but] does not reasonably provide enablement for all antibodies that bind to a polypeptide...comprising SEQ

ID NO: 1 or variants or fragments thereof." Office action at 4, emphasis omitted. Applicants respectfully traverse this ground for rejection.

The present specification describes how to make and use an antibody that specifically binds to: (a) a polypeptide consisting essentially of SEQ ID NO: 1, (b) a polypeptide with protein phosphatase activity comprising a sequence at least 90% identical to SEQ ID NO: 1, (c) an enzymatically active fragment of SEQ ID NO: 1, and (d) an immunogenic fragment of SEQ ID NO: 1.

1. The specification is enabling for antibodies that bind to SEQ ID NO: 1 and fragments and variants thereof

With regard to (a), the examiner conceded that an antibody that binds SEQ ID NO: 1 is enabled by the present specification. Office action at 6. Concerning (b)-(d), that a skilled artisan could readily identify polypeptides with phosphatase, enzymatic, or immunogenic activity that are at least 90% homologous to SEQ ID NO: 1 without undue experimentation. Nevertheless, in the interest of expediting prosecution, applicants have amended the claims to recite 95% sequence identity. Exemplary support for this amendment can be found on page 14, line 4-5.

In view of the foregoing arguments, it is respectfully requested that the present rejections be withdrawn.

CONCLUSION

Reconsideration of the present application in view of the foregoing amendments and arguments is kindly requested.

It is respectfully urged that the present application is now in condition for allowance. Early notice to that effect is earnestly solicited.

Examiner Steadman is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application

Respectfully submitted,

Date: May 24, 2004

By _____

Kristel Schorr
Patent Agent
Registration No. 55,600

FOLEY & LARDNER LLP
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 672-5574
Facsimile: (202) 672-5399